

QIMA Decision Rule for Reporting Statements of Conformity

This summary is not intended to be exhaustive nor should it be construed as legal advice. It is intended primarily as a general overview for introductory purposes.

1. Introduction

The 2017 revisions to the ISO/IEC 17025 standard include a requirement for test reports to include Statements of Conformity. In general, a Statement of Conformity describes whether a test result meets or does not meet a specified requirement. Additionally, in ISO/IEC 17025:2017, a new term “Decision Rule” was introduced, which is a “rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement”. Essentially, a decision rule specifies pass/fail criteria. Measurement uncertainty relates to the margin of doubt that exists for the result of any measurement, as well as how significant the doubt is.

Although the term “Decision Rule” is new, it is not a new concept as a similar requirement was mentioned in ISO/IEC 17025:2005, which stated that “When statements of conformance are made, the uncertainty of measurement shall be taken into account.”

When a statement of conformity to a specification or standard is required, the decision rule selected is to be communicated to and agreed with the customer. Decision rules need to be documented and need to take risk into account. The test results with a Statement of Conformity need to be clearly identified as such, including which specifications are met or not met, and what decision rule has been applied. A decision rule for a non-numerical result, such as whether or not a toy contains a small part, is simple as there is essentially no margin of doubt – either it contains a small part or it does not. For numerical results, such as chemical tests, the decision rule is more complex.

QIMA has established a global Standard Operating Procedure relative to how we select a decision rule when we report client results according to the requirement in ISO/IEC 17025:2017 (see Figure 1). When a statement of conformity is required, the QIMA decision rule will be applied when no decision rule is inherent in the law, regulation, standard, specification or client’s requirement.

2. QIMA Decision Rule Selection Process

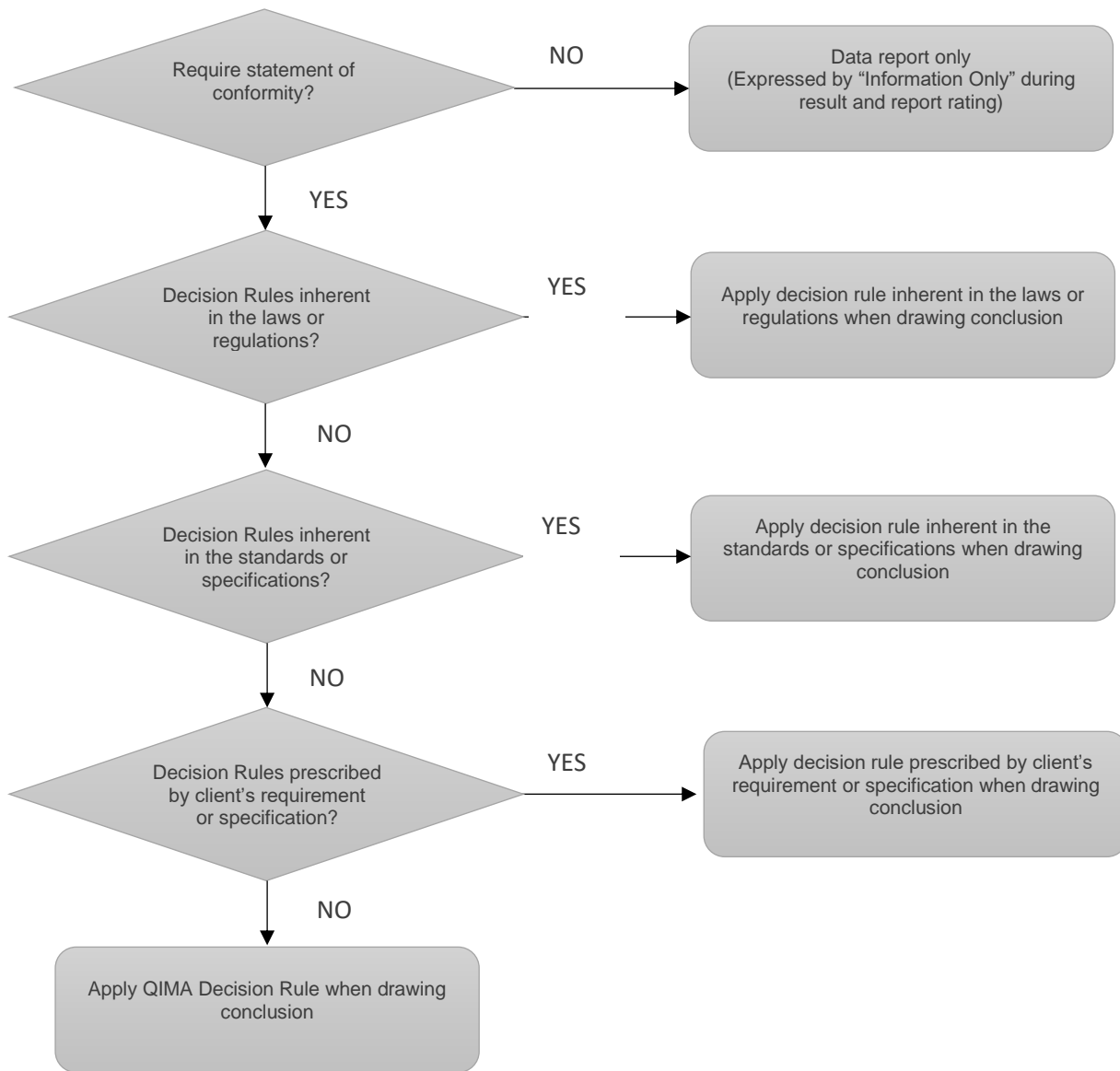


Figure 1

3. QIMA Decision Rule

For non-numerical results (e.g. observation, grading, rating):

A statement of conformity will be reported directly according to the test result and the specified requirement / specification.

For numerical results:

A statement of conformity shall be reported based on the expanded uncertainty with a 95% confidence interval. When the measured value +/- the expanded uncertainty with a 95% confidence interval overlaps the limit, no declaration of conformity can be made.

The influence of expanded uncertainty on numerical results can be divided into ten cases illustrated in Figures 2 and 3 below:

For maximum requirement limit:

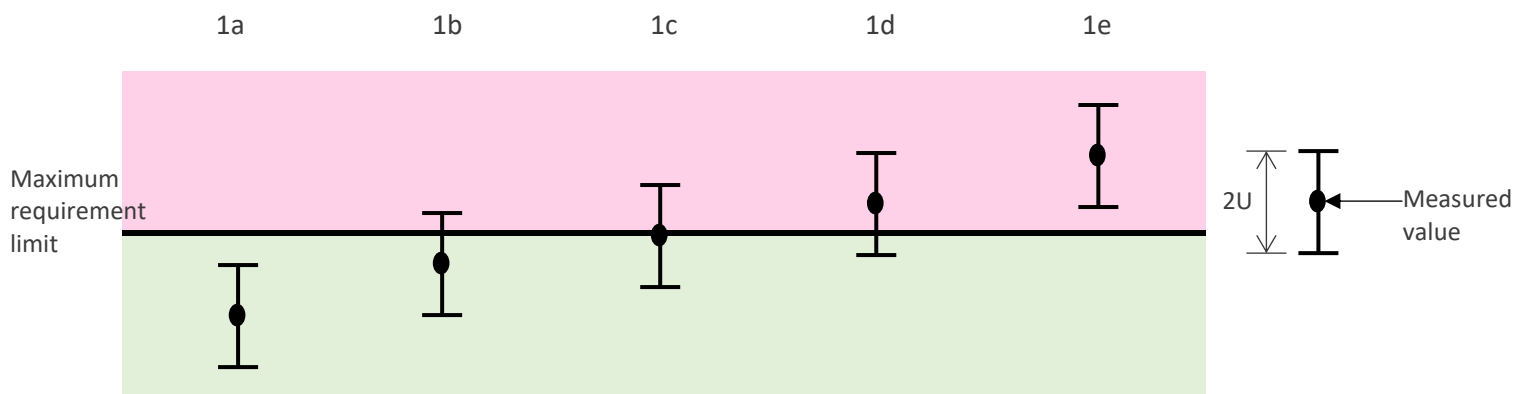


Figure 2

For minimum requirement limit:

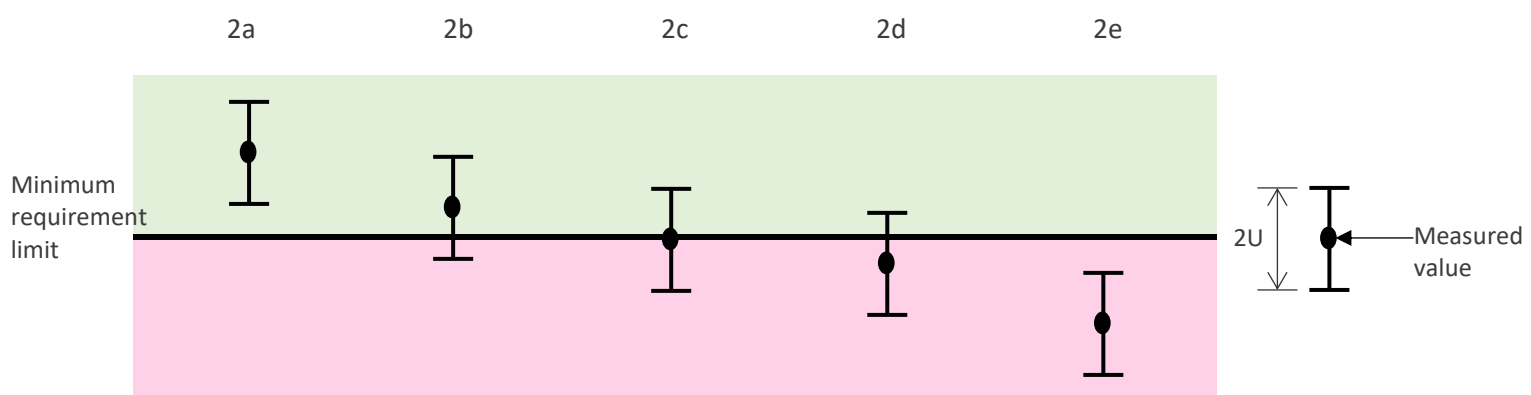


Figure 3

Notes: U = expanded uncertainty calculated by the QIMA laboratories of the site.

- Case 1a and 2a: When the measured value is extended up or down by the expanded uncertainty and the results all fall in green areas, a statement of meeting the requirements of the specification is declared, expressed by

"Pass". The false accept risk is up to 2.5%.

- Case 1e and 2e: When the measured value is extended down or up by the expanded uncertainty and the results all fall in pink areas, a statement of not meeting the requirements of the specification is declared, expressed by "Fail". The false reject risk is up to 2.5%.
- Case 1b-d and 2b-d: When the measured value is extended down or up by the expanded uncertainty and the results fall in both green and pink areas, the laboratory is unable to determine the conformity of the result, expressed by "Inconclusive".

(Version 3, effective date 24-Feb-2023)

Previous QIMA Decision Rule accessible here:

- [CRD_QIMA Decision Rule-V2](#)
- [CRD_QIMA Decision Rule-V1](#)

启迈 QIMA 关于报告符合性声明的判定规则

本摘要并非详尽无遗，亦不应被解释为法律意见。本文件旨在提供一个概括性介绍。

1. 引言

ISO/IEC 17025:2017 修订包含了测试报告含有符合性声明的要求。符合性声明一般是用来描述测试结果是否满足规定要求。此外，ISO/IEC 17025:2017 亦引进了一个新的术语“判定规则”，它的定义是“当声明与规定要求的符合性时，描述如何考虑测量不确定度的规则”。实际上，判定规则说明了符合或不符合的准则。测量不确定度与测量结果存在的可疑性以及可疑程度相关。

虽然“判定规则”是一个新的术语，但它不是一个新的概念。因为在 ISO/IEC 17025:2005 中“作出符合性声明时，应考虑测量不确定度”已经提到类似的要求。

当对某个规则或者标准作符合性声明时，判定规则的选择应与客户沟通并得到客户的同意。判定规则需要文件化，而当中的风险亦应被考虑。符合性声明时应清晰标识适用的测试结果，包括满足或者不满足的规范和应用的判定规则。非数值结果的判定规则很简单直接，例如判定一个玩具是否含有小部件，实际上怀疑的余地很小—要么含有要么不含有小部件。对于数值型结果，例如化学测试，判定规则更为复杂。

启迈 QIMA 根据 ISO/IEC 17025:2017 的要求制定了当报告结果时如何选择判定规则的全球通用操作流程(见图 1)。当需符合性声明时，如果法律、法规、标准或客人均未规定判定规则将会使用启迈 QIMA 的判定规则。

2. 启迈 QIMA 判定规则选择流程

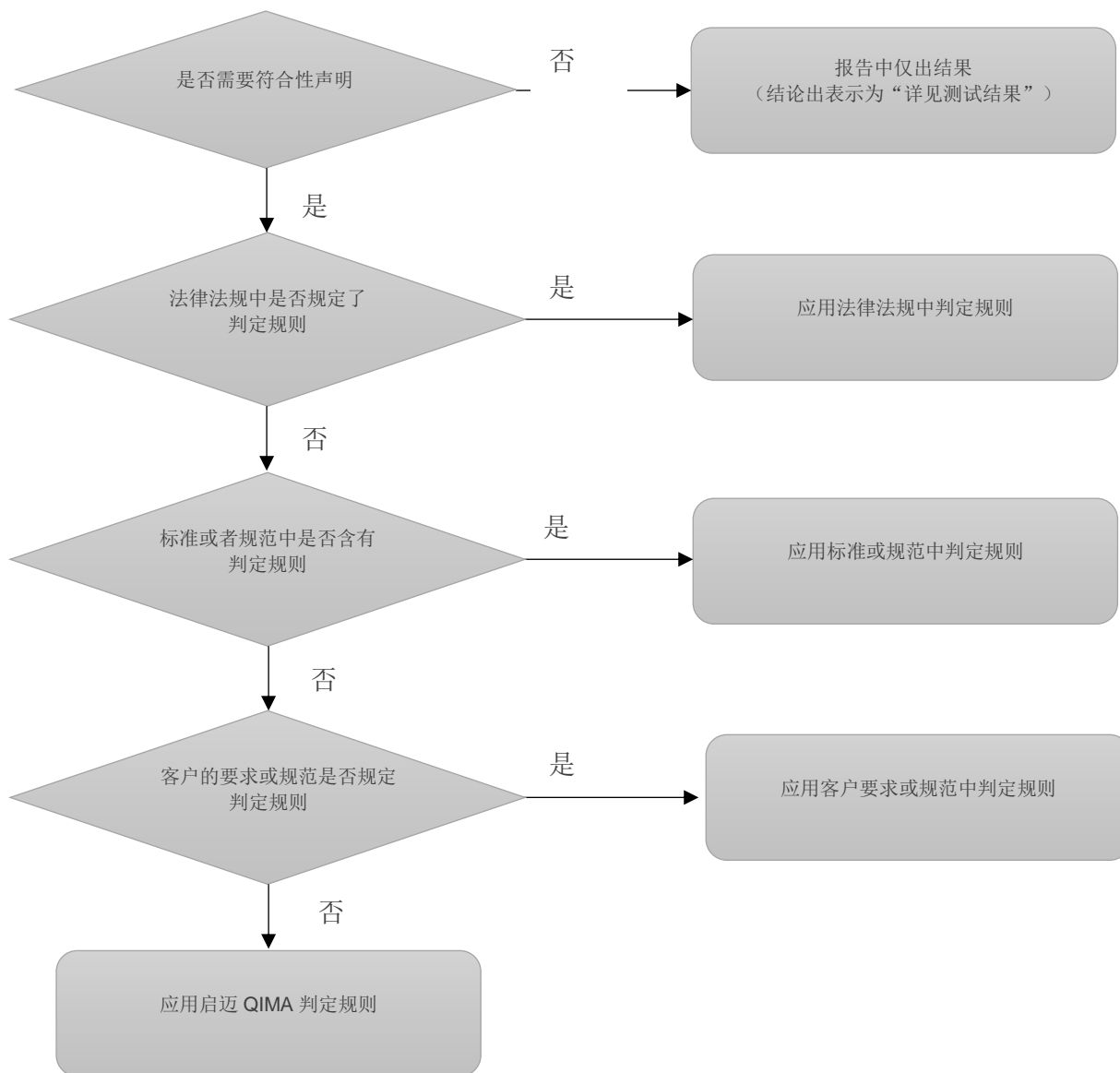


图 1

3. 启迈 QIMA 判定规则

非数值结果（例如：观察法、级别、评级）：

报告将根据测试结果和规定要求直接给出符合性声明

数值结果：

符合性声明应基于 95%置信区间的扩展不确定度进行报告。当 95%置信区间的扩展不确定度的测量值于该限值时重叠时，不能声明符合性。

扩展不确定度对数值结果的影响可以分为 10 种情况，如下图 2 和图 3 所示：

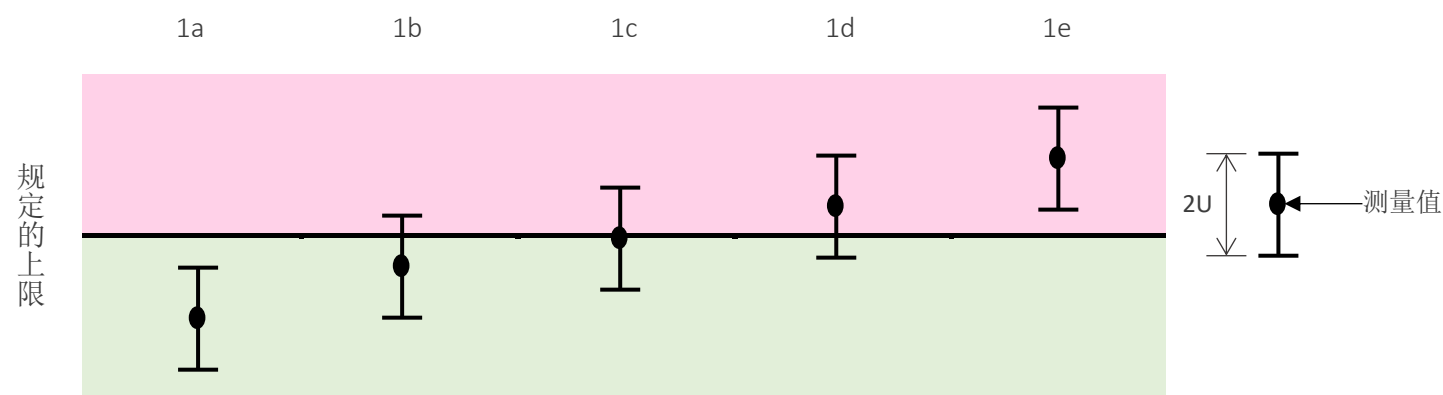


图 2

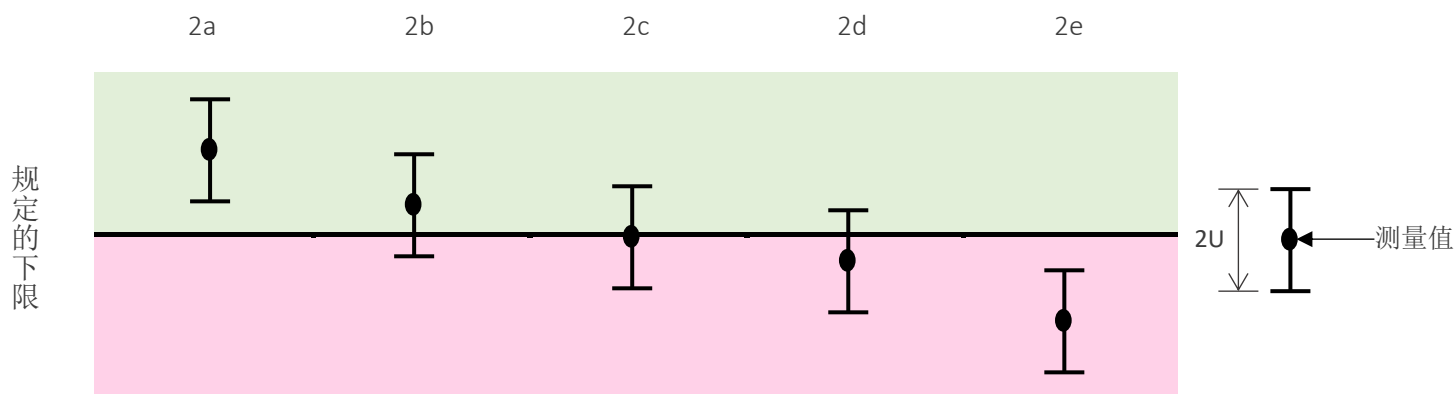


图 3

注释 U =由启迈 QIMA 实验室计算得出的扩展不确定度。

- 情况 1a 和 2a:当测量值向上或向下延伸扩展不确定后，测量结果全部位于绿色区域，则声明满足规范要求，用“符合”表示。错误接受风险高达 2.5%。
- 情况 1e 和 2e: 当测量值向上或向下延伸扩展不确定后，测量结果全部位于粉红色区域，则声明不满足规范要求，用“不符合”表示。错误拒绝风险高达 2.5%。
- 情况 1b-d 和 2b-d: 当测量值向上或向下延伸扩展不确定后，测量结果位于绿色和粉红色区域，实验室不能确定结果的符合性，用“非结论的”表示。

（版本 3，生效日期 2023 年 02 月 24 日）

链接到启迈 QIMA 判定规则前版本：

- [CRD_QIMA Decision Rule-V2](#)
- [CRD_QIMA Decision Rule-V1](#)